



2523 04 MAY 14 10:23
ASSOCIATION OF AMERICAN RAILROADS

**Law Department
50 F Street, N.W.
Washington, D.C. 20001-1564**

Michael J. Rush
Associate General Counsel

Phone: (202) 639-2503
Fax: (202) 639-2868
E-Mail: mrush@aar.org

May 13, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2002N-0278 Prior Notice of Imported Food Under the
Public Health Security and Bioterrorism Preparedness and Response Act
of 2002

Dear Sir or Madam:

Enclosed are the comments of the Association of American Railroads for the
above docket.

2002N-0278

C322

BEFORE THE
FOOD AND DRUG ADMINISTRATION

2524 '04 MAY 14 10:23

DOCKET NO. 2002N-0278:
PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC
HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS
AND RESPONSE ACT OF 2002

COMMENTS OF
THE ASSOCIATION OF AMERICAN RAILROADS

The Association of American Railroads (AAR),¹ on behalf of itself and its member railroads, submits the following comments in response to the Food and Drug Administration's (FDA) reopening for comment the interim final rule governing prior notice for shipments of food entering the U.S. or being exported from the U.S.² These comments briefly reaffirm AAR's suggestion in its earlier comments in this proceeding that FDA establish a prior notice window for rail shipments of two hours to ten days. AAR also suggests that FDA permit railroads to use Line Release for food shipments.

The Prior Notice Window Should Be Between Two Hours and Ten Days

AAR previously observed that there is no logical basis for FDA's requirement for four-hours advance notice of shipments of food when the Bureau of Customs and Border Protection (CBP) requires only two-hours advance notice for imports of all cargo.³ AAR is pleased that FDA and CBP are investigating a uniform two-hours advance notice requirement.⁴

In its earlier comments, AAR also noted that FDA's requirement that notice be provided no more than five days in advance is problematic for certain rail shipments which are not time-

¹AAR is a trade association whose membership includes freight railroads that operate 76 percent of the line-haul mileage, employ 91 percent of the workers, and account for 94 percent of the freight revenue of all railroads in the United States; and passenger railroads that operate intercity passenger trains and provide commuter rail service.

²68 Fed. Reg. 58975 (Oct. 10, 2003).

³Compare FDA's four-hour requirement at 21 C.F.R. § 1.279(a)(2) with CBP's two-hour requirement at 19 C.F.R. § 123.91(a), 68 Fed. Reg. 68140, 68173 (Dec. 5, 2003).

⁴See 69 Fed. Reg. 19765 (Oct. 10, 2003).

sensitive.⁵ AAR cited grain shipments from western Canada, some of which take longer than five days to reach the border. Similarly, beer shipments from the Gulf Coast of Mexico can take more than five days to reach our southern border. The brokers providing the advance notices for these shipments have no way of knowing precisely how much time it will take for the shipments to reach the border. Since the shipments are not time-sensitive, often the railroads will not have precise target dates for when the shipments will reach the border, even after transportation has commenced.

A ten-day window would provide the necessary flexibility. In the normal course of transportation, rail shipments do not take longer than ten days to reach the border.

It is possible that the interim final rule's ceiling of five days on prior notice stems from a misinterpretation of the statutory requirement for prior notice. Section 381(m)(2)(A), 21 U.S.C., provides that notice shall "be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days." Literally read, the quoted language states that the Secretary cannot determine that the period of time needed to respond to advance notice cannot exceed five days. The language does not say that a party cannot voluntarily provide notice more than five days in advance.

Line Release

In the latest *Federal Register* notice, FDA states it is exploring using Free and Secure Trade (FAST) processing for food shipments. FAST is an expedited-clearance system for motor carriers available to carriers participating in CBP's Customs-Trade Partnership Against Terrorism (C-TPAT). While FAST is unavailable for rail shipments, CBP does have a process for expediting rail shipments – Line Release.⁶

AAR urges FDA to permit the use of Line Release for food shipments by rail. AAR's member railroads participate in C-TPAT. Thus, it would be discriminatory to permit the use of an expedited clearance system for motor carriers, but not rail transportation.

AAR recognizes that if Line Release were permitted for food shipments, FDA's requirement for a PN number would have to be accommodated. AAR would appreciate the opportunity to explore with FDA and CBP how that might be accomplished.

⁵21 C.F.R. § 1.279(b).

⁶The regulations governing Line Release are set forth at 19 C.F.R. §§ 142 et seq.

Thank you for the opportunity to comment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael J. Rush". The signature is fluid and cursive, with the first name "Michael" being more prominent than the last name "Rush".

Louis P. Warchot
Michael J. Rush
Counsel for the Association
of American Railroads
50 F St., N.W.
Washington, D.C. 20001
(202) 639-2503

May 13, 2004